SAT Report

PMN Number: **P-13-0131**
SAT Date: **12/7/2012**
Print Date: **8/19/2014**

Related cases: [redacted]

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	3	

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes

Routes of exposure:

Health: Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-13-0131
FATE: Estimations for anion MW 72 [redacted]
log Kow = 0.35 (M)
log Koc = 0.16 (E)

log Fish BCF = 0.50 (E)
log Fish BAF = 0.04 (E)
FATE: Estimations for typical [redacted]
log Kow = 7.35 (E)
log Koc = 5.36 (E)
log Fish BCF = 3.36 (E)
log Fish BAF = 1.65 (E)
[redacted]
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = low
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for lung toxicity caused by interference with the [redacted] balance of the lungs and irritation to eyes, lungs and mucous membranes from the [redacted] moiety.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	0.020		[redacted]
daphnid	**48-h**	**LC50**	0.002		[redacted]
green algal	**96-h**	**EC50**	0.001		[redacted]
fish	**_**	**chronic value**	0.001		[redacted]
daphnid	**_**	**chronic value**	0.001		[redacted]
algal	**_**	**chronic value**	0.001		[redacted]
Sewage Sludge	**3-h**	**EC50**	_		
Sewage Sludge	**_**	**Chronic Value**	_		

Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern	1	[redacted]

(ppb)		
SARs	[redacted]	
SAR Class	[redacted]	
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916

Focus Report

New Chemicals Program

PMN Number: **P-13-0131**

Focus Date:	12/13/2012 12:00:00 AM	Report Status:	Completed
Consolidated Set:			
Focus Chair:	Jeff Bauer	Contractor:	Jessica Baxter

I. Notice Information

Submitter: [redacted]

CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted] submitted concurrently with T-13-0004. Test market period is 45 days.

Other Uses: [redacted]

PV-Max: [redacted]

Manufacture: X

Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 3 **Comments:** ;

Occupational: 0-1 **Non-Occupational:** NR **Environmental:** NR

(1) **PBT:** 1 1 1 **Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox Category: amides and aliphatic amines

Related Cases/Regulatory History:

Health related Cases: [redacted]

Ecotox Related Cases: [redacted]

Regulatory History:
- REG NON 5E SNUR
- DENIED
- [redacted] - REG NON 5E SNUR
- FOCUS DROP
- GRANTED
- WITHDRAWN/FACE 5E
- GRANTED
- DR DISPO DROP

CRSS P2Rec: [redacted]

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. / When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. Please contact the PPE manufacturer for advice on what type of glove material may be suitable. Gloves should be replaced immediately if signs of degradation are observed. / Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is| recommended if gross

	exposure is possible. / Wear a face shield with chemical splash goggles.
Respirator:	Where concentrations in air may exceed the limits given in this section, the use of air supplied breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used. If respiratory protection is required, institute a complete respiratory protection program including selection, fit testing, training, maintenance and inspection.
Health Effects:	EYE CONTACT: May cause irritation with prolonged contact. / SKIN CONTACT: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. / INGESTION: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. The main hazard of methyl alcohol arises from its misuse as a drinking substitute for ethyl alcohol. As little as 15 ml of 40% methyl alcohol may cause death. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. / INHALATION: Toxic by inhalation. / AGGRAVATION OF EXISTING CONDITIONS: Skin contact may aggravate an existing dermatitis condition.
TLV/PEL (PMN or raw material):	- Methanol - 60 % - TWA - OSHA PEL (Z1) - Methanol - 60 % - TWA - ACGIH TLV - Methanol - 60 % - STEL - ACGIH TLV

Exposure Based Information:

Exposure Based Review:	Y	Exposure Based Review (Health):	N
Exposure Based Review (Eco):	Y	Exposure Based (Occupational):	No
Exposure Based Review (Non Occupatuional):	N	Exposure Based (Environmental):	

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value
Surface DW:			
Fish Ingestion:			
Ground DW:			0
Inhalation:			0
Water Releases:			0
Total Releases:			[redacted]
Consumer Exposure:			

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-13-0131
FATE: Estimations for [redacted]
log Kow = 0.35 (M)
log Koc = 0.16 (E)
log Fish BCF = 0.50 (E)
log Fish BAF = 0.04 (E)
FATE: Estimations for typical [redacted]
log Kow = 7.35 (E)
log Koc = 5.36 (E)
log Fish BCF = 3.36 (E)
log Fish BAF = 1.65 (E)
PMN Substance: [redacted]
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for lung toxicity caused by interference with the surfactant balance of the lungs and irritation to eyes, lungs and mucous membranes from the amine moiety.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	0.020(P)
Daphnid 48-h LC50:	0.002(P)
Green algal 96-h EC50:	0.001(P)
Fish Chronic Value:	0.001(P)
Daphnid ChV:	0.001(P)
Algal ChV:	0.001(P)

Ecotox values comments: Predictions are based on SARs for [redacted] with molecular weight adjustment; SAR chemical class = [redacted]; MW 441; [redacted] (P); log Kow = 7.35 (EPI, free amine); [redacted] pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration:	1

V. Summary of Exposures/Releases

Engineering Summary: P-13-0131

Exposures/Releases	Release	Release	Release
Scenario	**Manufacturing:** [redacted]	**Processing:** [redacted]	**Processing:** [redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Conservative	Output 2	Conservative
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	**Processing:** [redacted]	**Use:** [redacted]	**Use:** [redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	High End	High End	Conservative
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-13-0131

Exposures/Releases	Release	Release	
Scenario	**Use:** [redacted]	**Use:** [redacted]	
Sites	[redacted]	[redacted]	
Media	[redacted]	[redacted]	
Descriptor A	Output 2	Output 2	
Quantity A (kg/site/day)	[redacted]	[redacted]	
Frequency A (day/year)	[redacted]	[redacted]	
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Ban Pending Upfront Testing Decision Date: 12/13/2012
Type of Decision:

Rationale: P-13-0131 will be regulated under the TSCA 5(e) category ( ) Ban Pending Upfront Testing under the risk based authority for ecotoxicity concerns. Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible inhalation. Ecotoxicity hazard concerns were high based on EcoSAR predictions for . .. Risks to the environment were due to releases to water where the SWC of and exceeded the acute and chronic COC of 1 ppb. EAB did not include one release ( ) from because it was a direct release to the and EPA is unable to model this relese. The required ecotoxicity testing will be the chronic base set including Fish early life stage toxicity test (OPPTS Test Guidelines 850.1400), Daphnid chronic toxicity test (OPPTS Test Guidelines 850.1300), and Algal toxicity, (OPPTS Test Guidelines 850.4500). The fate testing will be the Ready biodegradability (OECD 301B). No CEB or EAB exposure based criteria were met. This case was submitted along with T-13-0004, which was denied as part of the sustainable futures project.

COC: Chronic – 1 ppb, Acute – 1 ppb

Summary of Exposures and Releases

Manu

Proc

Use

[redacted]

P2 Rec Comments:

Testing:

Final Recommended:

Health:

Eco:

Fate:

Other:

Briefing Paper

Case Number: **P-13-0131**
Hybrid: Risk- and Exposure-Based
Risk Based Ecotoxicity

Part I: Background Data

Program Manager: Virginia Lee
Technical Integrator:
Review Team: David Tobias, Sharon Austin
Meeting Date:
Day In Process: 84
Day 90: 03/25/2013

A. CBI Claims: several
B. Submitter: [redacted]
C. Chemical Identity: [redacted]
D. Chemical Class:
Ecotox: [redacted]

E. Structure:

[redacted]

F. Physical/Chemical properties:

VP: Measured Torr @ 25 C
Est. <0.000001 Torr @ 25 C
s-H2O: Measured g/L
MW: 440.72 g/mol
Phys State: Neat: [redacted]
Manufacturing: [redacted]
Process/Form: [redacted]
End Use: [redacted]

G. Volume:
H. Use:

[redacted]

I. Test Data Submitted:
J. MSDS:

MSDS: Yes
Label: No

General equipment: General ventilation is recommended. Use local exhaust ventilation if necessary to control airborne mist and vapor. / When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. Please contact the PPE manufacturer for advice on what type of glove material may be suitable. Gloves should be replaced immediately if signs of degradation are observed. / Wear chemical resistant apron, chemical splash goggles, impervious gloves and boots. A full slicker suit is| recommended if gross exposure is possible. / Wear a face shield with chemical splash goggles.

Respirator: Where concentrations in air may exceed the limits given in this section, the use of air supplied breathing apparatus is recommended. In event of emergency or planned entry into unknown concentrations a positive pressure, full-facepiece SCBA should be used. If respiratory protection is required, institute a complete respiratory protection program including selection, fit testing, training, maintenance and inspection.

Health Effects: EYE CONTACT: May cause irritation with prolonged contact. / SKIN CONTACT: May cause irritation with prolonged contact. Toxic in contact with skin. Methanol may be absorbed through the skin and cause central nervous system effects which may result in permanent visual changes including blindness. / INGESTION: Not a likely route of exposure. May cause nausea and vomiting. Can cause central nervous system depression. Toxic if swallowed. The main hazard of methyl alcohol arises from its misuse as a drinking substitute for ethyl alcohol. As little as 15 ml of 40% methyl alcohol may cause death. Sublethal doses may cause central nervous system effects and may result in permanent visual changes including blindness. / INHALATION: Toxic by inhalation. / AGGRAVATION OF EXISTING CONDITIONS: Skin contact may aggravate an existing dermatitis condition.

K. SAT Ratings:

Human Health: 1-2 ; Environment: 3 ;

L. Focus Results: P-13-0131 will be regulated under the TSCA 5(e) category (amides and aliphatic amines) Ban Pending Upfront Testing under the risk based authority for ecotoxicity concerns. Human health hazard concerns were low-moderate for inhalation exposures. Potential risks to workers were mitigated by negligible inhalation. Ecotoxicity hazard concerns were high based on EcoSAR predictions for [redacted]. .. Risks to the environment were due to releases to water where the SWC of [redacted] and [redacted] exceeded the acute and chronic COC of 1 ppb. EAB did not include one release [redacted]) from [redacted] because it was a direct release to the [redacted] and EPA is unable to model this relese. The required ecotoxicity testing will be the chronic base set including Fish early life stage toxicity test (OPPTS Test Guidelines 850.1400), Daphnid chronic toxicity test (OPPTS Test Guidelines 850.1300), and Algal toxicity, (OPPTS Test Guidelines 850.4500). The fate testing will be the Ready biodegradability (OECD 301B). No CEB or EAB exposure based criteria were met. This case was submitted along with T-13-0004, which was denied as part of the sustainable futures project.

COC: Chronic – 1 ppb, Acute – 1 ppb

Summary of Exposures and Releases

Manu

[redacted]

[redacted]

Proc

[redacted]

[redacted]

Use

[redacted]

[redacted]

Part II: New Information

The submitter provided further information about the use scenario. [redacted] CEB and EAB revised their reports to indicate there are no longer water releases during manufacturing, processing or use. EAB gave the PMN an EAB drop.

Part III: Recommendation and Rationale

The program manager recommends P-13-131 be dropped from further review with a non-5(e) SNUR for a water trigger of 1 ppb because the PMN substance no longer poses an ecorisk as described in the amended PMN. The water trigger is based on the estimated chronic COC of 1 ppb. The recommended testing in the SNUR will be the chronic eco base set (fish, daphnid, and algae) and ready biodeg (OECD 301).

Part IV: Risk Summary

A. Health Effects:

Not absorbed through the skin, poor absorption from the GI tract; moderate absorption from the lung (analog). Concern for lung toxicity caused by interference with the surfactant balance of the lungs and irritation to eyes, lungs and mucous membranes from the amine moiety.

B. Environmental Effects:

Ecotox: predicted (P) and measured (M) toxicity value is mg/L (ppm) are:

Fish 96-h LC50:	0.020(P)
Daphnid 48-h LC50:	0.002(P)
Green algal 96-h EC50:	0.001(P)
Fish Chronic Value:	0.001(P)
Daphnid ChV:	0.001(P)
Algal ChV:	0.001(P)

C. Environmental Releases and Exposures:

D. Risk Estimates:

Part V: Exposure Criteria Met

Exposure Based Review (Chemistry):	● Yes ○ No	**Exposure Based Review (Health):**	○ Yes ● No
Exposure Based Review (Ecotox):	● Yes ○ No	**Exposure Based Review (Occupational):**	○ Yes ● No
Exposure Based Review (Non-Occupational):	○ Yes ● No	**Exposure Based Review (Environmental):**	○ Yes ○ No

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value

Part VI: Tests

Final Testing Recommendation
Health:
Eco:
Fate:
Other:

Comments:

Part VII: Other Factors

A. Substitutes:

B. Benefits:

C. Other Uses: [redacted]

D. Other:

Part VIII: Regulatory History

[redacted] - REG NON 5E SNUR
[redacted] - DENIED
[redacted] - REG NON 5E SNUR
[redacted] - FOCUS DROP
[redacted] - GRANTED
[redacted] - WITHDRAWN/FACE 5E
[redacted] - GRANTED
[redacted] - DR DISPO DROP

Comments:

Last Updated by

Document Created by Virginia Lee **on** 03/18/2013